Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of expressive writing on posttraumatic stress disorder and hopelessness in mothers with premature neonate hospitalized in Neonatal Intensive Care Unit

Protocol summary

Study aim
The effect of expressive writing on PTSD and hopelessness in mothers with premature neonate

Design
A non-randomized clinical trial with control and intervention groups on 70 mothers with premature babies

Settings and conduct
Location: the NICU of Esfahan Shahid Beheshti Hospital. The demographic information questionnaire of the mother and the baby will be completed during the first week after delivery. Then during the fourth week using the PPQ and Beck hopelessness questionnaire; Mothers with a score higher than six from the PPQ and any score from the Beck Questionnaire (because it does not have a cutoff point) will be included in the study. The expressive writing and how to write it for the intervention group is explained and they are asked to write in a private and quiet place, regardless of grammar about their deepest feelings and thoughts regarding the birth and hospitalization of their baby in the NICU . Writing three times a week (every other day) and each time will be for at least 15 minutes. The control group will only receive routine care. Then, after two to four weeks , PPQ and Beck's questionnaire will be completed again by the mothers of the two groups and they will be compared with before the intervention.

Participants/Inclusion and exclusion criteria
Inclusion criteria:18-year-old,literate,with premature babies, a score higher than six in the PPQ Exclusion criteria: history of suffering from PTSD, addiction and hospitalization of the baby for less than ten days

Intervention groups
In order to prevent the exchange of information, first all mothers who meet the entry criteria will be selected as the control group. After the discharge of the control group, sampling of the intervention group will begin. The control group does not receive any intervention and the intervention group will write expressive writing.

Main outcome variables
Posttraumatic stress disorder, Hopelessness

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230305057623N1**
Registration date: **2023-04-15, 1402/01/26**
Registration timing: **prospective**

Last update: **2023-04-15, 1402/01/26**
Update count: **0**

Registration date
2023-04-15, 1402/01/26

Registrant information

Name
Behnaz Soltanpour

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 31 3651 8095

Email address
b.soltanpour@stu.ssu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-05-04, 1402/02/14

Expected recruitment end date
2023-09-05, 1402/06/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of expressive writing on posttraumatic stress disorder and hopelessness in mothers with premature neonate hospitalized in Neonatal Intensive Care Unit

Public title

The effect of expressive writing on stress and hopelessness in mothers with premature neonate

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Mothers 18 years and older if they want to participate in the research Being literate (having at least a high school education) Iranian and fluent in Persian language Mothers with premature neonate less than 37 weeks Obtaining a score higher than six from the PPQ questionnaire Not having a hearing problem

Exclusion criteria:

History of post-traumatic stress disorder Drug addiction, use of anti-anxiety and depression or psychotropic drugs up to one month before sampling Existence of acute stressful situations during the last six months A history of being in the NICU and having a premature baby Mothers' use of other stress reduction methods Taking care of the baby by other family members other than the mother Genetic disease in the baby Hospitalization of the baby less than ten days

Age

From **18 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Yazd University of Medical Sciences

Street address

Professor Hesabi Boulevard, Safaeiye

City

Yazd

Province

Yazd

Postal code

8915813135

Approval date

2023-02-28, 1401/12/09

Ethics committee reference number

IR.SSU.REC.1401.103

Health conditions studied

1

Description of health condition studied

posttraumatic stress disorder

ICD-10 code

F43.1

ICD-10 code description

Post-traumatic stress disorder (PTSD)

2

Description of health condition studied

Hopelesness

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Post-traumatic stress disorder

Timepoint

During the fourth week after birth (first stage) and after two to four weeks of the first stage

Method of measurement

Perinatal Posttraumatic Stress Disorder Questionnaire

2

Description

hopelessness

Timepoint

During the fourth week after birth (first stage) and after two to four weeks of the first stage

Method of measurement

Beck Hopelessness Questionnair

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: the mothers in the intervention group are asked to write in a private and quiet place, regardless of grammar about their deepest feelings and thoughts regarding the birth and hospitalization of their baby in the intensive care unit.
Category
Other

2

Description
Control group: There is no intervention
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Beheshti Hospital
Full name of responsible person
Behnaz Soltanpour
Street address
Shahid Motahari Ave
City
Esfahan
Province
Isfehan
Postal code
8184853541
Phone
+98 31 3236 7001
Email
beheshti@mui.ac.ir
Web page address

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Yazd University of Medical Sciences
Full name of responsible person
Amin Salehi Abarghuei
Street address
Shahid Docror Bahonar Square
City
Yazd
Province
Yazd
Postal code
8916978477
Phone
+98 35 3724 0171
Email
samat@ssu.ac.ir
Web page address
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Yazd University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Yazd University of Medical Sciences
Full name of responsible person
Behnaz Soltanpour
Position
Student
Latest degree
Bachelor
Other areas of specialty/work
Anesthesiology
Street address
No.O1,Pardis12 Complex,Basij Alley,Kharazmi2 Ave,Qadir Ave,Sepahanshahr
City
Esfahan
Province
Isfehan
Postal code
8179916386
Phone
+98 31 3651 8095
Email
behnaz.slt@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Yazd University of Medical Sciences
Full name of responsible person
Zahra Pourmovahed
Position

Professor Assistant

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

Khovidak Road, Emam hosein Boulevard

City

Yazd

Province

Yazd

Postal code

8916978477

Phone

+98 35 3836 7668

Email

movahed446@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Behnaz Soltanpour

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Anesthesiology

Street address

No.O1,Pardis12 Complex,Basij Alley,Kharazmi2 Ave,Qadir Ave,Sepahanshahr

City

Esfahan

Province

Isfehan

Postal code

8179916386

Phone

+98 31 3651 8095

Email

behnaz.slt@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available